



PATENT APPLICATION

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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re application of

Docket No: Q67950

Yoshihide MURAKAMI, et al.

Appln. No.: 10/028,914

Group Art Unit: 1771

Confirmation No.: 2679

Examiner: Victor s. Chang

Filed: December 28, 2001

For: SUBSTRATE FILM FOR ADHESIVE SHEET AND ADHESIVE SHEET USING THE
SAME

SUBMISSION OF APPEAL BRIEF

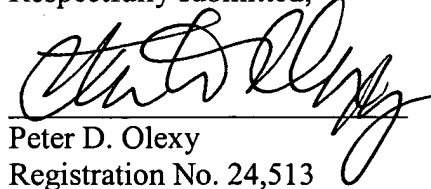
MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith please find an Appeal Brief. A check for the statutory fee of \$500.00 is attached. The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account. A duplicate copy of this paper is attached.

Respectfully submitted,


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WASHINGTON OFFICE

23373

CUSTOMER NUMBER

Date: March 20, 2006



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APPEAL BRIEF UNDER 37 C.F.R. § 41.37

MAIL STOP APPEAL BRIEF - PATENTS

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the provisions of 37 C.F.R. § 41.37, Appellant submits the following:

Table of Contents

I. REAL PARTY IN INTEREST	2
II. RELATED APPEALS AND INTERFERENCES.....	3
III. STATUS OF CLAIMS	4
IV. STATUS OF AMENDMENTS	5
V. SUMMARY OF THE CLAIMED SUBJECT MATTER	6
VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL	7
VII. ARGUMENT	8
CLAIMS APPENDIX.....	19

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APPEAL

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I. REAL PARTY IN INTEREST

The real party in interest is Nitto Denko Corporation, by virtue of an assignment executed by the Appellants on September 16, 1999, and submitted for recordation to the assignment Branch of the U.S. Patent and Trademark Office. The assignment was recorded on October 13, 1999, at Reel 010315, Frame 0144.

II. RELATED APPEALS AND INTERFERENCES

To the best of the knowledge and belief of the Appellants, the assignee and the undersigned, there are no other appeals or interferences before the Board of Appeals and Interferences that will directly effect or be effected by the Board's decision in the present appeal.

III. STATUS OF CLAIMS

Claims 17-18 are pending in the application.

Claims 17-18 are rejected.

Claims 17-18 are being appealed.

Claims 17-18 are set forth in their entirety in the Claims Appendix submitted herewith.

IV. STATUS OF AMENDMENTS

Two (2) Amendments Under 37 C.F.R. § 1.116 were filed in response to the final Office Action mailed on August 18, 2005.

The first Amendment Under 37 C.F.R. § 1.116 was dated November 18, 2005 and included amendments to the claims. The examiner did not enter the claim amendments contained in the first Amendment dated November 18, 2006. *See*, Advisory Action dated January 31, 2006.

The Second Amendment Under 37 C.F.R. § 1.116 was dated January 17, 2006 and included amendments to the claims. The Second Amendment dated January 17, 2006 canceled Claims 1-16 and 19-20 and amended Claim 17 by deleting the subject matter of canceled Claim 5 from Claim 17. The examiner entered these amendments to the claims on January 31, 2006.

A Notice of Appeal was filed on January 18, 2006. The filing on January 18, 2006 did not include an amendment to the claims.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

The present invention relates to an adhesive sheet using a substrate film for the adhesive sheet.

Claim 17 is an independent claim, drawn to an adhesive sheet. The adhesive sheet comprises an adhesive layer and a single layer substrate film, where the adhesive layer is formed on at least one surface of the substrate film. The substrate film consists essentially of an elastomer resin and a hydrophilic polymer. The hydrophilic polymer has a tensile modulus of elasticity higher than that of the elastomer resin. Further, the tensile modulus of elasticity of the substrate film is lower in a saturated water absorption state than in a dry state. When the substrate film is in combination with the adhesive sheet and the adhesive sheet is adhered to the skin, the tensile modulus of elasticity of the substrate film also decreases. The adhesive sheet has improved flexibility and skin follow-up property.

Claim 18 depends from Claim 17. It recites that the adhesive sheet is used for skin adhesion.

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The issues presented for appeal are:

(A) whether the examiner erred in rejecting Claims 17-18 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention; and

(B) whether the examiner erred in rejecting Claims 17-18 under 35 U.S.C. § 103(a), as being unpatentable over U.S. Patent Number 5,607,687 to Bezwada *et al.* ("Bezwada '687") in view of U.S. Patent Number 4,541,426 to Webster *et al.* ("Webster '426").

VII. ARGUMENT

(A) Rejection under 35 U.S.C. § 112, second paragraph

The Rejection

Claims 17-18 have been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Examiner takes the position that Claim 17-18 fails to clarify whether the single layer substrate film is being claimed or some combination of it with an adhesive sheet and the adhesive sheet is adhered to the skin.

The Error In The Rejection

Claim 17-18 are definite, in that Claims 17-18 particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Why Claims 17-18 are patentable under 35 U.S.C. § 112, second paragraph

Claims 17-18 are clearly drawn to the adhesive sheet rather than the substrate film. The second paragraph of 35 U.S.C. § 112 recites that “[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.” 35 U.S.C. § 112, second paragraph (2005). The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent to which patent protection affords. All Dental Prodx, L.L.C. v. Advantage Rental Products, Inc., 309 F.3d 774, 779; 64 USPQ2d 1945, 1949 (Fed. Cir. 2002) (citing Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 28-29 (1997)).

The Federal Circuit has explained that the second paragraph of section 112 contains two requirements: “first, [the claim] must set forth what ‘the applicant regards as his invention,’ and second, it must do so with sufficient particularity and distinctness, i.e., the claim must be sufficiently ‘definite.’” Solomon v. Kimberly-Clark Corp., 216 F.3d 1372, 1377; 55 USPQ2d 1279, 1282 (Fed. Cir. 2000). In determining whether the claim is sufficiently definite, the courts analyze whether “one skilled in the art would understand the bounds of the claim when read in light of the specification.” Personalized Media Communs., L.L.C. v. ITC, 161 F.3d 696, 705; 48 USPQ2d 1880, 1888 (Fed. Cir. 1998).

In the present case, a person of ordinary skill in the art would understand the bounds of the Claims 17-18 when read in light of the specification.

Claim 17 is clearly drawn to “[a]n adhesive sheet.” Claim 17, by itself, also provides that the adhesive sheet comprises the adhesive layer and the substrate film. Further, the specification describes that:

[t]he adhesive sheet of the present invention is characterized in that an adhesive layer is provided on at least one surface, i.e., one surface or both surfaces, of the substrate film for [the] adhesive sheet of the present invention.

See, page 18, lines 16-19. Based on this teaching in the specification, a person skilled in the art would understand that Claim 17, drawn to “[a]n adhesive sheet,” would be referring to “the adhesive sheet of the present invention” rather than the “substrate film for the adhesive sheet of the present invention.”

Additionally, Claim 17 recites that “when the substrate is in combination with the adhesive sheet and the adhesive sheet is adhered to skin, the tensile modulus of elasticity of the

substrate film decreases.” However, the condition under which the tensile modulus is provided fails to alter whether the substrate film itself is being claimed or whether the adhesive sheet is being claimed. In this regard, Claim 17 is definite for the purposes of 35 U.S.C. § 112, second paragraph. A person skilled in the art would understand that the adhesive sheet is being claimed in Claim 17.

Further, Claim 18 depends from Claim 17, reciting that the adhesive sheet is used for skin adhesion. A person of ordinary skill in the art would understand the bounds of skin adhesion. Therefore, Claim 18 is definite for the purposes of 35 U.S.C. § 112, second paragraph.

(B) Rejection under 35 U.S.C. § 103 (a)

The Rejection

Claims 17-18 have been rejected under 35 U.S.C. § 103(a), as being unpatentable over Bezwada ‘687 in view of Webster ‘426. The Examiner takes the position that a person of ordinary skill in the art would have been motivated to modify the bioabsorbable polymeric sheet disclosed in Bezwada ‘687 with the dressing disclosed in Webster ‘426. The Examiner asserts that the polyoxaester disclosed in Bezwada ‘687 reads on the hydrophilic polymer recited in Claim 17. The Examiner also asserts that the phrase “consisting essentially of” in Claim 17 fails to exclude the claimed substrate film from the teachings of Bezwada ‘687. In effect, the Examiner asserts that Bezwada ‘687 is deficient only in that it lacks the teaching that a layer of adhesive is formed on the surface of the bioabsorbable polymeric sheet. See, page 5 of the Office Action mailed on April 14, 2005. The Examiner looks to Webster ‘426 to make up for the

deficiency, referring to the disclosure that the dressing thereof is useful for treating lesions of the skin. Id.

The Error In The Rejection

The error in the rejection is that the combination of Bezwada '687 in view of Webster '426 does not establish a *prima facie* case of obviousness against Claims 17-18.

Why Claims 17-18 are patentable under 35 U.S.C. § 103 (a)

Applicants respectfully submit that Webster '426 fails to make up for the deficiencies of Bezwada '687. Further, a person of ordinary skill in the art would not have been motivated to combine Bezwada '687 with Webster '426.

Claim 17 recites that the claimed adhesion sheet comprises an adhesive layer and a single layer substrate film. The substrate film is uniquely adapted to be used with the claimed adhesive sheet. The substrate film consists essentially of an elastomer resin and a hydrophilic polymer. The tensile modulus of elasticity of the hydrophilic polymer is higher than that of the elastomer resin. The specification teaches that elastomers are materials that immediately restore the original shape when an external force is removed. See, page 8, lines 17-20 of the specification. Further, the specification teaches that the hydrophilic polymer may be a polyvinyl pyrrolidone, polyethylene oxide, polyacrylic acid, polyvinyl alcohol, polyvinyl methyl ether-maleic anhydride copolymer, alginic acid carboxymethyl cellulose, and cross-linked products of those polymers. See, page 9, lines 16-20 of the specification.

In contrast, Bezwada '687 discloses bioabsorbable polymer blends containing polyoxaesters as its main component and a second polymer. See, col. 2, lines 10-60 of Bezwada

‘687. Bezwada ‘687 discloses that the polyoxaester has a first divalent repeating unit of formula I and a second repeating unit selected from those represented by formulas II, III, and XI. See, col. 2, lines 14-30. Bezwada ‘687 fails to expressly teach that all polyoxaesters have a tensile modulus of elasticity higher than that of an elastomer resin. Instead, Bezwada ‘687 teaches that the polyoxaesters thereof are hydrolytically unstable and that it provides for the bioabsorbable properties of the polymer because it readily breaks down in to small segments when exposed to bodily tissue. See, col. 5, lines 57-62. For example, Bezwada ‘687 teaches that the polyoxaester may be a 3,6-dioxaoctanedioic acid dimethyl ester. See, col. 10-11, Example 1 of Bezwada ‘687. Further, Bezwada ‘687 teaches that examples of the second polymer include polyether polyurethanes, polyester polyurethanes, and polyvinyl pyrrolidone. See, col. 6, lines 10-23. Bezwada ‘687 teaches that the bioabsorbable polymers may be used for surgical operations, such as surgical clips, staples, and sutures. See, col. 6, lines 41-45.

With respect to Webster ‘426, the first two (2) sentences in Webster ‘426 are as follows:

[t]he invention relates to a dressing useful in treating lesions of the skin. More particularly, this invention relates to a laminate dressing which has a reduced tendency to adhere to lesions of the skin.

See, col. 1, lines 4-7 of Webster ‘426.

Based on these teachings, Webster ‘426 fails to make up for all of the deficiencies in Bezwada ‘687. To establish *prima facie* obviousness of a claimed invention, the prior art must teach or suggest all claim limitations of the claimed invention. MPEP 2143.03. Contrary to the Examiner’s assertions, a person of ordinary skill in the art would have recognized that Bezwada ‘687 is at least deficient in that it fails to teach or suggest (1) the adhesive layer and (2) that the

hydrophilic polymer having a tensile modulus of elasticity higher than that of the elastomer.

Given that Webster '426 is relied upon for disclosing an adhesive layer, Webster '456 fails to make up for the deficiencies of Bezwada '687.

The Examiner asserts that the hydrophilic polymer recited in Claim 17 reads on polyoxaester disclosed in Bezwada '687, even though Bezwada '687 fails to expressly teach the tensile modulus of elasticity of the polyoxaesters thereof. Where the Examiner has reason to believe that a limitation is an inherent characteristic of the cited art, the Examiner possesses the authority to require an applicant to prove that the subject matter shown to be in the cited art does not possess the characteristic on which the Examiner relies. Ex parte Skinner, 1986 Pat. App. LEXIS 4; 2 USPQ2d 1788 (Bd. Pat. App. & Int. 1986). Nevertheless, before the Examiner can place this burdensome task onto the applicant, the Examiner must provide some evidence or scientific reasoning to establish the reasonableness of the Examiner's belief that the feature is necessarily inherent in the cited art. Id. The burden of proof is the same, whether the rejection is based on inherency under 35 U.S.C. § 102 or *prima facie* obviousness under 35 U.S.C. § 103. The Examiner cannot establish the inherency of the feature by showing that the feature may be present in the cited art. MPEP 2112 (IV). In general, the standard for inherency requires the feature to be a natural result of the explicit teachings of the cited art. Perricone v. Medicis Pharmaceutical Corp., 432 F.3d 1368, 1377; 77 USPQ2d 1321, 1327 (Fed. Cir. 2005). For example, the Examiner may establish inherency, where the claimed and cited art products are identical or substantially identical, or are produced by identical or substantially identical processes. Ex parte Anderson, 1991 Pat. App. LEXIS 12; 21 USPQ2d 1241 (Bd. Pat. App. & Int.

1991). Moreover, an invitation to investigate is not an inherent disclosure. Metabolite Laboratories Inc. v. Laboratory Corp. of America Holdings, 370 F.3d 1354, 1367; 71 USPQ2d 1081, 1091 (Fed. Cir. 2004).

Here, the Examiner has incorrectly placed this burden on Applicants to provide evidence that the hydrophilic polymer is distinct from the polyoxaesters disclosed in Bezwada '687. The Examiner has set forth no scientific principle showing that each of the polyoxaesters disclosed in Bezwada '687, in fact, has a tensile modulus of elasticity higher than what the elastomer has. The Examiner's basis for shifting the burden onto Applicants incorrectly compares the hydrophilic polymer with the polyether polyurethanes, polyester polyurethanes, and polyvinyl pyrrolidones disclosed in Bezwada '687.¹ Bezwada '687 teaches that polyether polyurethanes, polyester polyurethanes, and polyvinyl pyrrolidone are examples of the second polymer rather than the polyoxaesters. See, col. 6, lines 10-23 of Bezwada '687. The Examiner's comparison would incorrectly require the hydrophilic polymer (e.g., polyvinyl pyrrolidone) to have a higher tensile modulus of elasticity than that of the second polymer (e.g., polyvinyl pyrrolidone). Based on such teachings identified in Bezwada '687, Bezwada '687 fails to establish that the polyoxaesters necessarily have a tensile modulus of elasticity higher than the elastomer. See, MPEP 2112 (IV). The polyoxaesters are also not substantially similar to the example hydrophilic polymers taught in Application. The teachings identified in Bezwada '687 even fail to amount to "an invitation to investigate," which the court has said is an incorrect standard for

¹ The Examiner asserts that "Bezwada '687 teaches the same elastomer resins and hydrophilic polymer (i.e., polyether polyurethanes, polyester polyurethanes, and polyvinyl pyrrolidones) as the instant invention." See, page 4, lines 1-3 of the Office Action dated April 14, 2005.

an inherent disclosure. See Metabolite Laboratories, 370 F.3d at 1367; 71 USPQ2d at 1091. As such, the Examiner has not shown that Bezwada '687 inherently teaches that the polyoxaesters thereof has a tensile modulus of elasticity higher than that of the elastomer.

Even assuming that some of the polyoxaesters thereof inherently have a tensile modulus of elasticity higher than that of the elastomer, the "consisting essentially of" language in Claim 17 demonstrates that substrate film recited in Claim 17 fails to read on the polymer blend disclosed Bezwada '687. Claim 17 recites that the substrate film consisting essentially of an elastomer and a hydrophilic polymer having a tensile modulus of elasticity higher than that of the elastomer. An explicit disclosure of a genus fails to amount to an inherent description of all of the species of the genus. See, Metabolite Laboratories, 370 F.3d at 1367; 71 USPQ2d at 1091. In the present case, the Examiner has failed to identify where Bezwada '687 teaches using the polyoxaester on the basis that they have a tensile modulus of elasticity higher than that of the elastomer. As a result, Bezwada '467 teaches generically that any of the polyoxaesters thereof can be used in the polymer blend thereof. Such teachings in Bezwada '687 fail to amount to a teaching that only those polyoxaesters having a tensile modulus of elasticity higher than that of the elastomer are effectively present in the polymer blend thereof.

The "consisting essentially of" language also provides that ingredients that materially affect the basic and novel characteristic(s) of a composition may not be presented in the claimed composition. In re Janakirama-Rao, 317 F.2d 951; 137 USPQ 893 (Fed. Cir. 1963). Bioabsorbability would materially alter the basic characteristic of the substrate film recited in Claim 17, because bioabsorbability in the claimed adhesive sheet would make the adhesive sheet

useless. In this regard, Bezwada '687 fails to teach that the polymer blend thereof consists essentially of the second polymer and those polyoxaesters.

Additionally, these teachings in Bezwada '687 fail to suggest modifying the polyoxaesters to those having a tensile modulus of elasticity higher than that of the elastomer. The teaching in Bezwada '687 regarding the bioabsorbability of the polyoxaester fails to suggest the modification to the polyoxaesters. If the modification of the cited art proposed by the Examiner would change the principle of operation of the art being modified, then the teachings of the reference are not sufficient to render the claims *prima facie* obvious. In re Ratti, 270 F.2d 810; 123 USPQ 349 (CCPA 1959). In other words, the Examiner's proposed combination of the prior art cannot destroy the teachings of the prior art reference being modified. In this case, the proposed modification to Bezwada '687 would destroy the bioabsorbant properties of the polyoxaester thereof. Bioabsorbaility in the claimed adhesive sheet would make the adhesive sheet useless. If the polyoxaester disclosed in Bezwada '687 is not bioabsorbant, then it would undermine its use as a suture. See, col. 2, lines 10-17 of Bezwada '687.

Further, the Examiner has failed to identify a scientific principle or evidence showing that the hydrophilic polymer recited in Claim 17 reads on the second polymer disclosed in Bezwada '687. The Examiner has failed to show that each of second polymers have a tensile modulus of elasticity having a higher tensile modulus of elasticity than that of the polyoxaesters. As described above, a disclosure of a genus also does not inherently disclose all species within that broad category. Metabolite Laboratories, 370 F.3d at 1367; 71 USPQ2d at 1091. Although Bezwada '687 teaches that polyvinyl pyrrolidones may be used as the second polymer thereof,

Bezwada '687 provides polyvinyl pyrrolidones as one of several examples of the second polymer. However, the claimed tensile modulus of elasticity is also not a natural result of all of the second polymers disclosed in Bezwada '687. A person of ordinary skill in the art would not have recognized that the tensile modulus of elasticity is a characteristic common among the second polymer disclosed in Bezwada '687, if it is a common characteristic at all. In this regard, the teachings in Bezwada '687 regarding the second polymers fails to inherently teach the hydrophilic polymer recited in Claim 17.

Applicants also respectfully submit that a person of ordinary skill in the art would not have been motivated to combine Bezwada '687 with Webster '426. The Examiner bears the initial burden of factually supporting any *prima facie* conclusion of obviousness. MPEP §2142. In particular, the initial burden is on the Examiner to find some motivation or suggestion to make the claimed invention in light of the prior art teachings. The suggestion to modify must be "clear and particular." In re Sang Su Lee, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433-1434 (Fed. Cir. 2002); Winner Int'l Royalty Corp. v. Ching-Rong Wang, 202 F.3d 1340, 1348-1349, 53 USPQ2d 1580, 1586-1587 (Fed. Cir. 2000).

In the present case, the dressing disclosed in Webster '426 has no relationship to the polymer blend disclosed in Bezwada '687. Webster '687 teaches that the dressing thereof has a reduced tendency to adhere to skin lesions. Webster '687 teaches that the dressing layer thereof has a first layer that swells and so expands when in contact with a wet surface. See, col. 3, lines 25-32 of Webster '426. In start contrast, Bezwada '687 teaches that the polyoxaesters thereof are hydrolytically unstable, such that it breaks down into small segments when exposed to moist

bodily tissue. See, col. 5, lines 57-62 of Bezwada '687. In this regard, a person of ordinary skill in the art would not have been motivated to combine the teachings in Bezwada '687 with the teachings in Webster '426.

Withdrawal of the rejections is respectfully requested.

Unless a check is submitted herewith for the fee required under 37 C.F.R. §41.37(a) and 1.17(c), please charge said fee to Deposit Account No. 19-4880.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

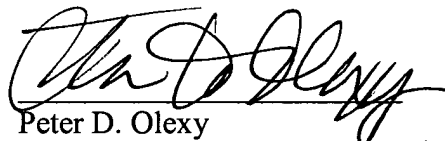
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WASHINGTON OFFICE

23373

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Date: March 20, 2006

CLAIMS APPENDIX

CLAIMS 17-18 ON APPEAL:

17. An adhesive sheet comprising an adhesive layer formed on at least one surface of a single layer substrate film for the adhesive sheet consisting essentially of an elastomer resin and a hydrophilic polymer having a tensile modulus of elasticity higher than that of the elastomer resin, wherein the single layer substrate has a tensile modulus of elasticity in a saturated water absorption state lower as compared to a tensile modulus of elasticity in a dry state such that when the substrate is in combination with the adhesive sheet and the adhesive sheet is adhered to skin, the tensile modulus of elasticity of the substrate film decreases, which improves the flexibility and skin follow-up property of the adhesive sheet.

18. The adhesive sheet as claimed in claim 17, wherein the sheet is used for skin adhesion.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37
U.S. Application No. 10/028,914

Attorney Docket No. Q67950

EVIDENCE APPENDIX:

None.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37
U.S. Application No. 10/028,914

Attorney Docket No. Q67950

RELATED PROCEEDINGS APPENDIX

None.